NHS

National Treatment Agency
for Substance Misuse

Injectable heroin (and injectable methadone)

Potential roles in drug treatment

Full guidance report

May 2003

National Treatment Agency

More treatment, better treatment, fairer treatment

The National Treatment Agency (NTA) is a special health authority, created by the Government in 2001, with a remit to increase the availability, capacity and effectiveness of treatment for drug misuse in England.

The overall purpose of the NTA is to: double the number of people in effective, well-managed treatment from 1998 to 2008; and to increase the proportion of people completing or appropriately continuing treatment, year on year. This is in line with the UK drugs strategy targets.

Injectable heroin (and injectable methadone): potential roles in drug treatment

This guidance has been developed by the NTA in consultation with experts in the field. It provides initial guidance for drug treatment practitioners on the potential role of injectable heroin and injectable methadone substitute maintenance prescribing in local drug treatment systems. The guidance is designed to complement with the current Department of Health clinical guidelines – *Drug misuse and dependence: guidelines on clinical management* (Department of Health, 1999).

This document and a separate executive summary are available on the NTA website at www.nta.nhs.uk.

© National Treatment Agency, London, May 2003

The text in this document may be reproduced free of charge in any format or media without requiring specific permission. This is subject to the material not being used in a derogatory manner or in a misleading context. The source of the material must be acknowledged as the National Treatment Agency. The title of the document must be included when being reproduced as part of another publication or service.

National Treatment Agency
5th Floor, Hannibal House, Elephant and Castle, London SE1 6TE
Tel 020 7972 2214 Fax 020 7972 2248
Email nta.enquiries@nta.gsi.gov.uk www.nta.nhs.uk

Contents

Executive summary 3

1 Introduction 7

1.1 Aim of guidance 7
1.2 Rationale 7
1.3 Key messages 7
1.4 Using this document 7
1.5 Role of expert groups 8
1.6 Implementation 8

2 Consensus on clinical evidence 9

3 Principles for injectable maintenance prescribing 10

4 Background 11

4.1 Policy context 11
4.2 Current practice issues 12

5 The evidence base 15

5.1 Summary 15
5.2 The research evidence 15

6 Provision of injectable maintenance prescribing 20

6.1 Licences 20
6.2 Models of delivery 20

7 Clinical eligibility and management 22

7.1 Eligibility criteria 22
7.2 Outcome measurements 23
7.3 Optimised oral maintenance drug treatment 24

Appendices

Appendix 1 Excerpts from *Drug misuse and dependence – guidelines for clinical management* (Department of Health,1999) 25

Appendix 2 Optimised oral maintenance drug treatment 27

References 30

Executive summary

Background

The Government has recognised that the existing Department of Health 1999 guidelines, *Drug misuse and dependence: guidelines on clinical management* (henceforth the *Clinical guidelines*) gives only limited guidance on the topic of injectable opioid substitution treatment. Additional guidance on the prescribing of injectable opioids is timely as new evidence has emerged in recent years. In addition, *Models of care* (NTA, 2002), the major new commissioning framework for drug treatment, requires that prescribing drug treatment modalities should be fully integrated within a wider, co-ordinated system. Hence the role of injectable maintenance prescribing requires further clarification within this context.

This document provides initial guidance for practitioners in drug treatment services on the potential role of injectable heroin and injectable methadone substitute maintenance prescribing in local drug treatment systems.

Published by the National Treatment Agency (NTA) and based upon consultation with expert groups, it presents the outcome of a majority consensus approach, based on the evidence available to date and on the experience of expert practitioners.

The guidance is designed to be consistent with the *Clinical guidelines* (1999) and provide additional advice on the basis of expert review of the evidence.

Summary of key messages

The document has four key messages:

1. The prescribing of injectable substitute opioid drugs for maintenance may be beneficial for a minority of heroin misusers. The document makes preliminary recommendations on eligibility criteria.

2. Future maintenance prescribing of injectable diamorphine or injectable methadone should only be undertaken if it is in line with eight principles identified by the expert groups. This is essentially a new standard of injectable drug treatment to that previously provided in England. Applying these principles in practice, sets a high standard for delivery of this treatment intervention, in recognition of the risks involved.

3. Services should be improved for patients already in receipt of injectable maintenance prescriptions for heroin or methadone, but where patients are stable, maintaining this stability is paramount.

4. Priority should be given to improving the effectiveness of oral maintenance treatment (on methadone or buprenorphine) for the majority of patients in all drug action team areas in England.

The evidence base

The published evidence base on injectable maintenance treatment is weak in many respects. However, the expert group agreed that some conclusions could be drawn from both international and UK studies. These are that:

- Injectable maintenance treatment is most appropriate for long-term heroin addicts who have not responded to oral maintenance treatment

- Where injectable heroin and methadone maintenance prescriptions are provided as part of a comprehensive treatment programme, both may have beneficial effects on health, social functioning and crime reduction.

However, since the majority of evidence relates to patients who have “failed” oral programmes, there is a need to probe the causes of “failure”.

Poor outcomes from oral maintenance programmes may relate to the characteristics of the patient, or to the way in which the treatment is delivered. There is good evidence about the components of effective oral maintenance treatment, but in practice many services fall far short of delivering to optimal standards. Particular areas for improvement relate to increasing average maintenance dosage levels, improving care planning, addressing the lack of supervised consumption and encouraging patients to have psycho-social support including education and housing.

Principles guiding injectable maintenance prescribing

This guidance recommends that injectable maintenance prescribing should only be undertaken in line with eight principles.

1. Drug treatment comprises a range of treatment modalities which should be woven together to form integrated packages of care for individual patients.

2. Substitute prescribing alone does not constitute drug treatment. Substitute prescribing requires assessment and planned care, usually with other interventions such as psycho-social interventions. It should be seen as one element or pathway within wider packages of planned and integrated drug treatment.

3. Within the substitute prescribing modality, a range of prescribing options are required for heroin misusers requiring opioid maintenance. Some options may carry more inherent risks than others (e.g. injectable versus oral options). Patients who do not respond to oral maintenance drug treatment should be offered other options in a series of steps. This would normally include:

    - oral methadone and buprenorphine maintenance, specifically optimised higher dose oral methadone or buprenorphine maintenance treatment, then
    - injectable methadone or injectable heroin maintenance treatment (perhaps in combination with oral preparations).

4. Injectable maintenance options should be offered in a local area that can offer optimised oral methadone maintenance treatment including adequate doses, supervised consumption and psycho-social interventions. This is essential to ensure oral drug treatment options have been fully explored prior to a trial of injectable maintenance treatment and to ensure smooth transition back to oral treatment if required.

5. Injectable and oral substitute prescribing must be supported by locally commissioned and provided mechanisms for supervised consumption. Injectable drugs may present more risk of overdose than oral preparations and have a greater value on illicit markets and hence may require greater levels of supervision.

6. Injectable maintenance treatment is likely to be long-term treatment with long-term resource implications. Clinicians should consider the move from oral to a trial of injectable preparations carefully, including long-term implications for the patient and drug treatment systems and involvement of services.

7. Specialist levels of clinical competence are required to prescribe injectable substitute drugs. Heroin prescribing also requires a Home Office licence.

8. The skills of the clinician should be matched with good local systems of clinical governance, supervised consumption and access to a range of other drug treatment modalities.

This guidance also recommends that there is need for further work around identifying the most effective models of delivery.

Clinical eligibility

The expert group reached some consensus on eligibility criteria, precautions and outcome measures. However, guidance on issues such as dose or the prescribing of combinations of oral and injectable preparations will require further work.

The agreed criteria are set out in full and relate to factors such as:

- age and drug usage
- willingness to comply with conditions such as supervision and monitoring, engagement in a range of care options, avoidance of some risky behaviours and of diverting prescriptions into illicit markets
- persistence of poor outcomes within an optimised oral programme.

The document outlines a range of precautions and outcome measures.

Optimised oral methadone services

The key elements of an optimised oral methadone service are described, with the following four crucial components being highlighted from the evidence-base:

- adequate doses following proper individualised assessment are important. Daily doses of 60mg to 120mg have consistently been shown to be more effective
- services with adequate supervision and monitoring of patients including care planning and supervised consumption (during initial stages or periods of instability) are more effective in reducing harm and improving outcomes
- services that strongly encourage involvement in psycho-social services (including counselling, education and support) have patients with better outcomes
- services with competent staff who can develop positive relationships with patients have better outcomes.

The expert groups noted that enforced detoxification or reduction regimes are associated with poor patient outcomes and are not recommended.

Additional issues raised by the expert group

Injectable treatments are falling

In recent years there has been a reduction in injectable prescribing in both absolute terms and as a proportion of overall opioid substitute treatments. This is partly because of the rise in oral methadone treatment. The availability of doctors who are licensed to prescribe heroin also varies widely between regions. Nationally there is a lack of specialist clinicians and in some regions the shortages are chronic.

Increasing reluctance of doctors to prescribe

Recent evidence has given some insights into reasons for the increasing reluctance of doctors to prescribe. They include concerns about:

- the lack of arrangements to supervise consumption
- resources to provide the service safely
- a perceived limited evidence base for the effectiveness of injectable maintenance treatments
- the appropriateness of this form of treatment
- risks of drug-related death and professional reprimands
- commitment to a long-term treatment.

Issues around supervised consumption

UK policy recognises that it is desirable for the consumption of all substitute drugs to be supervised during the initial stages of drug treatment and if a patient becomes unstable. This can reduces the risk of harm to the user from accidental overdose and the risk of diversion to illicit markets. However, in practice many local areas do not have arrangements for patients to consume substitute drugs under supervision. The expert group highlighted this issue as a source of concern.

Costs of injectable prescribing compared to oral programmes

Injectable maintenance treatment appears to be an expensive option. Whilst reliable figures are difficult to obtain, it is estimated that injectable maintenance treatment can cost between 5 to 15 times as much as oral maintenance treatment programmes. The NTA will explore costs in greater depth in 2003. However, it is important that commissioners and providers ensure that any new service responses to a lack of injectable treatment do not undermine the overall provision of drug treatment and that injectable maintenance treatment is targeted appropriately.

Recommendations

The key recommendations are that:

- **optimised oral methadone maintenance should be the maintenance treatment for the majority of heroin users**
- **injectable heroin and methadone treatments should be considered only for the minority of patients who are genuinely unresponsive to an optimised oral maintenance treatment approach**
- **injectable heroin and injectable methadone treatments based on this guidance should be seen as a new drug treatment modality requiring the development of new integrated care pathways.**

1 Introduction

1.1 Aim of guidance

This document provides initial guidance for drug treatment practitioners on the potential role of injectable heroin and injectable methadone substitute maintenance prescribing in local drug treatment systems.

Based upon consultation with expert groups, it presents the outcome of a majority consensus approach based on the evidence available to date and on the experience of practitioners in the field.

The guidance is designed to complement the current Department of Health clinical guidelines: *Drug misuse and dependence: guidelines on clinical management (1999)*, henceforth referred to as the *Clinical guidelines*.

1.2 Rationale

The document has been written for a number of reasons.

- The National Treatment Agency for Substance Misuse (NTA) was asked by the Government to develop evidence-based guidance on the appropriate prescribing of injectable heroin in the management of opioid dependence. This was undertaken in partnership with the Department of Health and groups of experts.
- Heroin prescribing is only covered briefly by the Department of Health's *Clinical guidelines* (1999) - see Appendix 1.
- There is an emerging evidence base on injectable heroin and methadone maintenance treatment from international trials and naturalistic studies in England.

1.3 Key messages

The document has four key messages:

1. The prescribing of injectable substitute opioid drugs may be beneficial for a minority of heroin misusers. The document makes preliminary recommendations on eligibility criteria.
2. Future maintenance prescribing of injectable heroin or methadone should only be undertaken if it is in line with eight principles identified by the expert groups. This is essentially a new standard of injectable drug treatment to that previously provided in England. Applying these principles in practice, sets a high standard for delivery of this treatment intervention, in recognition of the risks involved.
3. Services should be improving for patients already in receipt of injectable maintenance prescriptions for heroin or methadone. Where patients are stable, maintaining this stability is paramount.
4. Priority should be given to improving the effectiveness of oral maintenance treatment (on methadone or buprenorphine) for the majority of patients in all drug action team areas in England.

1.4 Using this document

For ease of use, the core recommendations of the expert groups in terms of clinical evidence and principles to underpin injectable services are presented immediately after the introductory section. The document then includes:

- background to the issue
- summary of the available evidence base
- clinical issues including eligibility criteria
- the importance of optimising the effectiveness of oral maintenance programmes.

The guidance does **not** cover:

- non-injectable forms of heroin
- the use of injectable opioids in reduction or detoxification regimes
- detailed clinical issues concerning injectable opioid drug treatment.

These issues will be discussed further by the expert groups and may be addressed in future guidance. It is envisaged that the NTA and Department of Health will continue to work with expert groups to develop additional guidance over the next year.

1.5 Role of expert groups

The Department of Health and the NTA convened a number of expert groups between February and December 2002. Members included doctors, nurses, researchers, service users, policy advisors, pharmacists and representatives from the Royal Colleges of Psychiatrists and General Practitioners.

An early recommendation of the expert group was that the guidance should cover both injectable heroin and injectable methadone drug treatment as they were deemed to have much in common and the evidence base for both was often entwined. This advice was embraced and is reflected in this document.

1.6 Implementation

An implementation plan has been designed to address a range of issues at national and local levels, including:

- the dissemination and promotion of the guidance
- the development of new models of injectable drug treatment
- improving services for existing patients receiving injectable prescriptions focussing on preserving patient stability
- improving oral maintenance treatment options in all areas in England
- national support projects to provide networks of peer support for specialist clinicians and additional development of protocols and guidance
- national pilots for new types of injectable maintenance drug treatment.

The implementation of improved oral maintenance drug treatment, improvements in injectable maintenance drug treatment and the development of new types of injectable drug treatment modalities will be monitored by the NTA over the next three years.

2 Consensus on clinical evidence

The following statements were agreed as consensus on 'clinical evidence' by the expert group based upon many years' experience of prescribing heroin and other injectable drugs.

Statements from the expert advisory group

1. We consider that the prescribing of injectable substitute opioid drugs, including heroin and methadone ampoules, may be of benefit for a minority of heroin misusers. **In principle this should be part of a range of potentially available drug treatment options, provided it is set in the context of a comprehensive drug treatment package.**

2. We consider the prescribing of heroin and other injectable opiate maintenance treatment is not a first-line treatment for dependent heroin users. **Injectable opioid maintenance treatment (including injectable heroin maintenance) is an exceptional treatment that should only be considered for patients who have not responded to optimised conventional oral maintenance treatment.**

3. We consider that there **may be greater inherent risks with injectable opioid treatment, when compared with the better-studied oral methadone maintenance (and other treatments, such as sublingual buprenorphine maintenance that has less risk of overdose).** These include greater risks of overdose, continued injecting harms and greater risks of diversion and abuse of medication. Formal consideration of the risks and benefits of injectable opioid treatment should be undertaken with all potential patients, particularly those who may be at highest risk.

4. We consider that these **risks and dangers (to the individual patient and to society at large) can be greatly reduced by adherence to practices and procedures which increase compliance with treatment**, and which reduce prescribing to inappropriate patients, erratic use and diversion to the illicit market.

5. We consider the assessment of potentially suitable patients, and the subsequent initiation of injectable opioid maintenance treatment, to be a task that requires considerable experience and expertise in the addictions field, and which should consequently be **undertaken by a competent specialist doctor* working in an appropriately supported treatment setting**.

6. We consider that the **wider safe provision of injectable opioid maintenance treatment requires substantial identifiable resources and facilities** (as recently established in Switzerland and the Netherlands). These are required in order to make possible the wider provision of injectable maintenance treatment options and thereby achieve these greater potential benefits to the patient and society whilst minimising adverse consequences.

* See Department of Health: *Drug misuse and dependence: guidelines on clinical management*, and NTA's *Resource pack for commissioners*, briefing 3.6 on community prescribing.

3 Principles for injectable maintenance prescribing

Following the advice of the expert group, the NTA recommends that:

- new maintenance prescribing of injectable drugs for drug misusers should only be undertaken if it is in line with the following eight principles. This is essentially a new standard of injectable treatment modality which should be developed and implemented for all new patients eligible for injectable maintenance treatment
- for patients already in receipt of injectable prescriptions, service providers and commissioners in local areas should work together to improve local services (if required) to bring them in line with the eight key principles. Patients' stability should be paramount in this instance. Additional guidance will be produced to advise on arrangements for such patients.

Eight principles underlying injectable maintenance prescribing

1. Drug treatment comprises a range of treatment modalities which should be woven together to form integrated packages of care for individual patients.
2. Substitute prescribing alone does not constitute drug treatment. Substitute prescribing requires assessment and planned care, usually with other interventions such as psycho-social interventions. It should be seen as one element or pathway within wider packages of planned and integrated drug treatment.
3. Within the substitute prescribing modality, a range of prescribing options are required for heroin misusers requiring opioid maintenance. Some options may carry more inherent risks than others (e.g. injectable versus oral options, frequency of injecting etc). Patients who do not respond to oral maintenance drug treatment should be offered other options in a series of steps. This would normally include:
   - oral methadone and buprenorphine maintenance, specifically optimised higher dose oral methadone or buprenorphine maintenance treatment, then
   - injectable methadone or injectable heroin maintenance treatment (perhaps in combination with oral preparations).
4. Injectable maintenance options should be offered in a local area that can offer optimised oral methadone maintenance treatment including adequate doses, supervised consumption and psycho-social interventions. This is essential to ensure oral drug treatment options have been fully explored prior to a trial of injectable maintenance treatment and to ensure smooth transition back to oral treatment if required.
5. Injectable and oral substitute prescribing must be supported by locally commissioned and provided mechanisms for supervised consumption. Injectable drugs may present more risk of overdose than oral preparations and have a greater value on illicit markets and hence may require greater levels of supervision.
6. Injectable maintenance treatment is likely to be long-term treatment with long-term resource implications. Clinicians should consider the move from oral to a trial of injectable preparations carefully including long-term implications for the patient and drug treatment systems and involvement of services.
7. Specialist levels of clinical competence are required to prescribe injectable substitute drugs. Heroin prescribing also requires a Home Office licence.
8. The skills of the clinician should be matched with good local systems of clinical governance, supervised consumption and access to a range of other drug treatment modalities.

4 Background

4.1 Policy context

Prescribing heroin and other injectable drugs to treat opioid dependence is not new. It has been accepted practice among some drug misuse specialists in England for decades – usually for a minority of their patients.

4.1.1 Hierarchy of treatment goals

For some years, a range of goals of drug treatment has been identified in the UK Advisory council on the Misuse of Drugs, ACMD 1988, 1989; *Task force to review services for drug misusers* 1996). These are:

- reduction of health, social and other problems directly related to drug misuse
- reduction of harmful or risky behaviours associated with the misuse of drugs (e.g. sharing injecting equipment)
- reduction of health, social or other problems not directly attributable to drug misuse
- attainment of controlled, non-dependent, or non-problematic, drug use
- abstinence from main problem drugs
- abstinence from all drugs.

  (From *Models of care*, NTA, 2002)

This hierarchy of goals endorses the principle of the need to reduce harm until the drug misuser is ready and able to come off drugs (Department of Health, 1999). In this context, "harm" includes social, medical, legal, and financial problems, as well as the direct physical consequences and risks involved in drug misuse.

Substitute prescribing options within drug treatment packages should therefore be seen in the context of a wider strategy to reduce drug-related harms to individuals and communities.

4.1.2 Current Department of Health guidelines

The Department of Health issues guidelines to identify optimal clinical practice for doctors in the UK. The current guidelines in this area are entitled *Drug misuse and dependence – guidelines for clinical management* (1999) (henceforth the *Clinical guidelines*)*.

The 1999 *Clinical guidelines* do not contain extensive recommendations on the prescribing of injectable methadone and heroin. The need to build on and update current guidelines was a driving force behind the rationale for this document.

The *Clinical guidelines* list five key observations in respect of injectable opiate treatment:

- injectable opiate maintenance has a definite role but is rarely used fairly
- there may be greater risks of diversion and consequent harms
- there may be a danger of aggravating chronicity
- substitute injectable prescribing requires the availability of initial and periodic supervised consumption
- specialist clinicians should accept responsibility to provide this exceptional treatment.

* The full text of the section in the *Clinical guidelines* concerning injectable prescribing is reproduced in Appendix 1 (pages 55-57 of the *Clinical guidelines*).

4.1.3 *Models of care*

Models of care (2002) sets out the new national framework for the commissioning of adult treatment for drug misuse.

Each local drug action team (DAT) area in England is expected to implement *Models of care* from October 2002 and to develop integrated local systems of drug treatment comprising four tiers of provision, locally agreed screening, assessment and referral mechanisms, care planning and co-ordination, integrated care pathways and monitoring.

Injectable drug treatment should be treated as a new modality requiring the development of new integrated care pathways within this system. It is envisaged that patients would require care planning, psycho-social interventions and enhanced care co-ordination to meet a range of needs.

4.2 Current practice issues

4.2.1 Licensing and competence requirements for prescribing injectable heroin and methadone for drug misuse

Currently, the prescribing of heroin for the treatment of addiction requires a doctor to hold a licence from the Home Office. The prescribing of injectable methadone does not, but this is recommended as an activity for specialist clinicians in the *Clinical guidelines* (1999).

A key issue around prescription heroin and methadone treatment is the shortage of specialist clinicians and inequalities in provision between regions.

According to Home Office data, there were 94 doctors licensed to prescribe heroin for the treatment of addiction in England in December 2002. The geographical spread of these practitioners was reported to be uneven with some regions having no license holders and other regions having over 30. The regional breakdown was given as:

Region	No. of licensed doctors
South West	8
South East	19
London	21
West Midlands	0
East Midlands	3
Eastern Region	4
North West	21
North East	5
Yorkshire and Humber	3

Other sources estimated that between 70 and 91 doctors held licences to prescribe heroin in 2000 in the UK, which may indicate that there may be some inaccuracies in the Home Office data (Stimson et al 2000). Only three doctors were licensed to prescribe heroin in Scotland or Northern Ireland in 2000.

Whilst the estimates may vary, there is no doubt that there is a chronic shortage of specialist clinicians and a pressing need to address regional variations.

4.2.2 Numbers of people receiving injectable prescriptions

It is difficult to obtain accurate estimates of the number of people receiving injectable treatment.

The available data suggests that about 450 patients currently receive heroin and about 3,000 receive injectable methadone. Both figures may include people who have received a mixture of maintenance and reduction treatment regimens.

The data suggests that injectable heroin and methadone prescribing has remained static or slightly declined in absolute terms and has substantially “withered away” as a proportion of the total population receiving substitute drug treatment.

In part, this is due to the growth in oral methadone prescribing. Whilst all substitute treatment has increased between 5 per cent and 15 per cent each year, the proportion of prescribed heroin has declined dramatically from 20 per cent in the 1970s to less than 0.5 per cent today. At the same time, injectable methadone has reduced from nine per cent of methadone prescriptions in 1995 to four per cent in 2001. (Strang et al 2003).

4.2.3 Why has injectable substitute prescribing declined?

Evidence from surveys

A survey of English and Welsh doctors licensed to prescribe heroin (Metrebian et al 2002), reported that the main reasons for the decline involved doctors' concerns about:

- the lack of supervision of treatment and the associated risks of diversion and abuse of prescribed medication
- resources to provide the service safely
- perceived limited evidence base for the effectiveness of injectable treatments.

In addition, a national survey of general practitioners in England (Strang et al unpublished 2001, Royal College of General Practitioners conference), indicated that, whilst there was substantial acceptance of the appropriateness of oral methadone maintenance in primary care settings, this was not the case for injectable substitute prescribing.

Over half of all GPs reported oral methadone maintenance was either "very appropriate" or "somewhat appropriate" in the management of the dependent opiate misusers in their practice. However, 93 per cent of GPs reported that they considered injectable methadone prescribing to be "not at all appropriate" and a further six per cent considered it only "somewhat appropriate" in a primary health care setting.

It is likely that there would be an even greater proportion of GPs who consider injectable heroin prescribing as "not at all appropriate".

Evidence from the expert groups

Some members of the expert group expressed reluctance to initiate new patients into injectable heroin because they had concerns about committing new patients to very long-term treatment.

Clinicians who prescribed heroin as a first line of treatment (beginning in the 1960s and 1970s), reported they did so in good faith, with the belief that patients would be provided with a host of other services which would encourage them to move on to oral maintenance treatment and, eventually, abstinence. They reported that this had not occurred and the resources to provide comprehensive treatment packages had not been consistently available. In retrospect they reflected that this practice may have contributed to a cohort of patients kept for decades on injectable maintenance prescriptions without being adequately encouraged towards healthier lifestyles.

4.2.4 Supervised consumption

UK policy has recently emphasised the need for greater capacity for supervision of substitution drug treatment.

The *Clinical guidelines* (1999) recommend supervised consumption for three months at the beginning of all substitute prescribing drug treatment options and that supervision is continued until patients have stabilised their drug use and social circumstances.

In some parts of England, this model has been followed with community pharmacists playing an important role in supervising patients taking oral methadone. However, in other areas, supervision is limited – particularly (but not exclusively) in rural localities.

An additional driver for greater supervision was highlighted by a report from the Advisory Council on the Misuse of Drugs (ACMD, 2000). This implicated substitute drug treatment (particularly methadone treatment) as a factor in both limiting the spread of HIV in England, *and* contributing to preventable drug-related overdose deaths. Accordingly, the report recommended greater supervision.

Clinicians on the expert group reported that whilst guidelines state new clients, and clients who destabilise, are usually required to have a period of supervised or partially supervised consumption, historically most clients receiving oral or injectable prescriptions are not required to consume their drugs under supervision. Take home doses are the norm in England.

Some clinicians reported that they do not have local resources to supervise daily consumption of oral methadone – let alone injectable heroin (or methadone) – which may need to be injected up to four times a day.

Lack of access to supervised consumption was therefore identified as a key area of concern by the expert advisory group.

4.2.5 Cost and cost-effectiveness of injectable substitute prescribing

Injectable substitute drug treatment is a relatively expensive drug treatment option. Calculating cost and cost-effectiveness of different types of drug treatment is complex and attempts to do so are compounded by a lack of agreement on appropriate methodology. The NTA is engaged in further work to provide more accurate and consistent unit costings of drug treatment modalities and options.

Strang et al (2003) estimated that injectable methadone represented 20 per cent of the methadone prescription drug costs in 2001 for four per cent of treatments. Indeed injectable methadone and heroin treatment has been estimated to cost between 5 to 15 times as much as oral methadone treatment, depending on the content of treatment packages and arrangements to supervise consumption.

Surveys of clinicians indicate that the cost of injectable heroin in particular is a prohibitive factor. In addition, it is recognised that the substitute prescribing of injectable heroin and methadone in the UK appears to be a long-term treatment which may limit long-term cost-effectiveness.

The NTA will explore issues of cost in greater depth. However, cost factors indicate that commissioners need to be able to ensure that the provision of injectable maintenance drug treatment does not undermine the overall quality of care for all patients. Where adequate access to optimised oral drug treatment options are not available to the majority of patients, it may be particularly difficult to demonstrate this.

The potentially “high cost and low volume” nature of injectable maintenance drug treatment indicates that it should be targeted at patients with high levels of need. These patients are, in any case, likely to incur high levels of costs to health and social care systems.

5 The evidence base

5.1 Summary

This document considers both published research and the clinical evidence of doctors. A range of evidence from Europe and the UK is listed in some detail below. This section also considers the evidence around why individuals "fail" within oral treatment and makes the case for prioritising the development of quality oral treatment. For ease of reference, the key findings and recommendations around the evidence base are summarised below.

Whilst the expert group recognised weaknesses in the evidence base, it considered that some broad conclusions may be drawn:

- Injectable maintenance treatment is most appropriately aimed at long-term heroin (or other opioid) misusers who have not responded to optimised oral maintenance treatment.
- Where injectable heroin and methadone prescription are provided as part of a comprehensive treatment programme, both may have beneficial effects on health, social functioning and crime reduction.
- The majority of evidence relates to patients who have "failed" oral programmes. This "failure" often arises because services are not being delivered to optimal standards.
- The evidence base for the effectiveness of oral methadone maintenance treatment is good. A key recommendation of this document is that local services should prioritise developing high quality oral methadone (and buprenorphine maintenance) treatment. This should be the first-line treatment for the majority of heroin misusers.

5.2 The research evidence

5.2.1 Limitations of the evidence base

The evidence around injectable methadone and heroin prescribing is weak in many respects. Significant questions remain unanswered or are only partially answered - particularly in the UK context. More research is required.

There is a lack of high quality research studies (such as randomised controlled trials). Also, the clinical evidence available is hampered by difficulties of comparison – both between the substitute drugs offered, and the models of service in which they are provided.

Some of the main limitations include:

- lack of comparison between injectable methadone and injectable heroin drug treatment
- lack of comparison between injectable drug treatments and optimised oral treatments
- lack of studies on client groups other than "oral methadone treatment failures" – optimised or not
- case studies where the findings cannot be generalised
- international studies where findings are not easily transferable to the UK.

Despite these caveats, the expert group did consider that some conclusions could be drawn.

5.2.2 Conclusions from the Swiss and Dutch heroin clinics

There have been two major European trials of "heroin clinics" since the mid-1990s. These took place in Switzerland and the Netherlands and involved treating over 1,000 patients in comprehensive programmes including supervised consumption and the provision of psycho-social drug treatment and social care.

The Dutch trial involved long-term heroin 'addicts' who had *not* responded to repeated treatment attempts with oral medication. They showed that injectable heroin maintenance:

- is feasible (i.e. it can be delivered safely)
- can be effective in retaining the patient in treatment over time
- can produce benefits in terms of improved health, social functioning and crime reduction.

The large Swiss trial involved 17 outpatient centres and 385 patients. Three quarters (76%) of patients receiving injectable heroin were retained for at least one year.

Improvements were seen in a range of domains including: reductions in illicit heroin use, cocaine and benzodiazepine use; and improvements in housing, employment, financial situations, injection-related damage and psychological health. The clinics had strict regimes involving injecting under supervision (up to) three times a day and also offering intensive psycho-social interventions. Many patients who left the programme went on to other drug treatments.

The disadvantages of this study included the fact that it did not have a control group taking oral methadone, and almost a quarter of patients also received oral methadone (Uchtenhagen A. et al, 1999).

Also of note is a study by Perneger et al (1999) which enrolled heroin users not in treatment and with a prior history of "poor performance" in oral methadone treatment. A considerable proportion of those randomised to conventional oral methadone treatment responded well – achieving abstinence (33 per cent) or very low levels of heroin use (19 per cent). Some oral methadone clients were randomly selected to join a waiting list for heroin prescribing. 62 per cent of these clients chose not to enrol in treatment with heroin when it became available for them six months later. Commencing treatment with prescribed heroin ampoules would have been unnecessary (and costly) in this client group.

In the Netherlands trial, 549 patients were treated in six cities between 1998 and 2001. Patients were heroin users who still used heroin daily and had poor physical and social functioning. All had repeatedly been treated with oral methadone doses of at least 60mg daily. Patients in the experimental group were prescribed heroin together with methadone for 6 or 12 months while the control group received only oral methadone. The patients who were prescribed injectable opioids demonstrated 25 per cent greater improvements in physical health, social functioning and psychological adjustment, relative to the control group. However, a follow-up study showed that within two months of stopping the treatment, the extra health gains had been lost. Other improvements were reduced criminality and reduced use of other illicit drugs, notably cocaine which had been used by 90 per cent of the patients. However, the study did not measure changes in illicit heroin use in the study group, which limits the lessons to be learnt from these trials (Van den Brink et al 2002).

5.2.3 Initial conclusions from UK studies

There has been little clinical research published on injectable methadone or heroin prescribing in the UK. Most published materials are descriptive and generally not based on trials as such. However, two recent English trials have been published, both based on injectable drug clinics set up within two large London drug specialist NHS services.

Metrebian et al (1998) studied 58 patients who were prescribed either injectable methadone or heroin after previously failing oral methadone treatment. Failure here included continuing to inject illicit heroin.

Patients were given a choice of injectable drug. 64 per cent chose heroin and 36 per cent chose methadone. There was no requirement for daily attendance or supervised consumption of drugs. Under two-thirds of patients (57 per cent) were retained for nine months, with most of the remainder being discharged for violation of the treatment protocol.

Of those retained, major improvements in health and social domains were found in both groups with changes evident early in treatment (i.e. after three months). There was a more mixed picture over a longer period: there were improvements in some areas such as HIV risk behaviour but increases in illicit drug use between the third and sixth months in treatment and also continuing criminal activity amongst some patients.

The second study, Strang et al (2000), tested the feasibility of supervised injecting at a drug clinic and identified which patients benefited most.

This study randomised 39 heroin misusers to either oral or injectable methadone maintenance treatment. There was a requirement for daily attendance during the week and drug taking was supervised at the clinic except at weekends.

Interviews at six months indicated that crime and illegal drug use were lower than at intake, and physical and psychological health had improved for all patients. People receiving injectable methadone demonstrated slightly better outcomes and reported significantly higher satisfaction with treatment. Patients with worse physical and psychological problems reduced their use of illicit heroin more while receiving injectable methadone. A requirement to return empty ampoules from weekend take-home doses to prevent diversion seemed to work well as an alternative to supervised consumption.

The supervised injecting clinic offered an opportunity to observe patients' injecting techniques and engage them in harm reduction. Although many patients had been injecting for a long time, many were found to have poor injecting techniques and demonstrated unsafe practice. Even with intensive input, advice and injection monitoring, venous access deteriorated for all patients (Cummins M., forthcoming, *Methadone matters*, chapter 11, section C).

5.2.4 Evidence from clinical practice in the UK

A recent review of the case notes of those in receipt of heroin prescriptions for heroin addiction (Metrebian et al - forthcoming report to NTA) concluded:

- Heroin prescribing for the treatment of heroin addiction remains rare in the UK.
- Current provision is determined by the history of the service, personal preferences of the prescribing doctor, and local attitudes towards the practice and costs of prescribing heroin.
- Doctors have a range of views on prescribing heroin as part of a drug treatment package. Some prescribe because they believe this is an important service. Others do so reluctantly because they have inherited patients in receipt of heroin prescriptions.
- The cost of heroin is prohibitive to commencing treatment and to long-term prescribing.
- There is wide variation in current practice including doses and care planning.
- There is little or no supervision of consumption.

Sell et al (2001) conducted an audit of 125 patients receiving prescriptions for injectable opioids from regional drug services in Manchester. Of these, 86 per cent received injectable methadone and 13 per cent received injectable heroin. This group were a "chronic addict population" who had, on average, been injecting for 16 years. Two-thirds were receiving oral methadone in addition to injectable drugs.

Interestingly, when asked if they could choose a drug, half (50 per cent) chose heroin whilst 31 per cent chose injectable methadone. A further question then asked which drug they believed would be best for their treatment. The proportion selecting heroin dropped to 34 per cent whilst 46 per cent selected injectable methadone.

Other audits of patients in the UK in receipt of injectable opioids via general practice have been described as "encouraging" (Ford and Ryrie, 1999, and Martin et al 1998).

Beaumont (2001) identified 107 GP practices as recently or currently prescribing injectable methadone. This amounted to 93 general practitioners treating 211 patients with injectable methadone. The majority (60 per cent) of these doctors were prescribing to only one patient. Within this group there was considerable variation in practice.

Some British experience suggests that only a minority of clients have made the transition to conventional treatment after a period of injectable treatment (Battersby et al 1992). This is different

from the experience of the Swiss and Dutch programmes where up to 25 per cent of clients moved to other drug treatment options (including abstinence-based treatment) within one year. This may be related to the stricter requirements of the European models in relation to attendance and supervised consumption.

However, a small UK study described an "enforced but gentle" transition for 14 patients from injectable to oral methadone in Shropshire (Myton and Fletcher, 2003). Of the 14 patients, eight stopped injecting and the remainder used oral methadone in addition to injecting heroin. Three years later, four patients had stopped all opiate use and six were maintained on oral methadone (five without illicit heroin use). A further two patients were receiving oral methadone maintenance from their GP and one was no longer in treatment. Authors concluded that it is possible to alter the formulation without losing clinical stability or patients stopping treatment, and that the offer of a transition period is helpful.

Research into practice briefing No 3: heroin prescribing

In conjunction with the guidance in this document, the NTA is publishing a summary of a recent review of heroin and injectable methadone prescribing in Europe and the UK. This is not a systematic review, but nevertheless provides a useful summary of the issues raised regarding the role and efficacy of injectable opioid drug treatment.

5.2.5 What constitutes failure to benefit from oral drug treatment?

The majority of research evidence on injectable heroin prescribing has focussed on those patients who have failed to benefit from oral methadone maintenance treatment. However, in the UK, "failure" in drug treatment may be due to a range of causes. In some circumstances these may be client related (e.g. persistent desire to continue heroin use). In others, poor outcomes may relate to how treatment is delivered.

The components of effective methadone treatment are well established (Ward, Mattick, Hall 1998) and four key factors have been identified:

- Higher doses of methadone following individualised assessment with clear, safe practices in increasing doses: There is a dose-response relationship in which higher daily doses of 60mg to 120mg (in particular above 80mg) have consistently been shown to be more effective than lower doses.
- Adequate levels of supervision and monitoring of clients: Regular treatment review and monitoring allows services to identify and respond to those clients experiencing problems. Supervised dosing is an important safety measure, particularly during induction and stabilisation periods or for 'unstable' clients.
- Participation in psychosocial services (e.g. counselling, social, housing and welfare support services): Clients who participate in psychosocial services tend to have better outcomes than those who do not. Most contemporary approaches to substitution treatment highlight the importance of encouraging (though not mandating) clients to participate in such services.
- Positive therapeutic relationships between clients and practitioners.

Research indicates that many clients in methadone maintenance treatment in the UK may receive sub-optimal treatment:

- Research into mean methadone doses found a mean methadone dose of 44 mg per day in a national survey of 25 per cent of pharmacies in England and Wales (Sheriden et al 1996).
- Research into supervised consumption of methadone showed that 45 per cent of methadone prescriptions in the south east of England were unsupervised (Strang and Sheridan 1998). Lack of supervised consumption of methadone has been associated with preventable drug-related death – particularly in the early stages of drug treatment (ACMD 2000).

- Carnworth and Merrill (2002) conclude that dose equivalence and correct therapeutic doses (for oral and injectable opioids) need re-examining in light of evidence that sub-optimal doses are common in the UK.
- Many service users in drug treatment have infrequent review and poor participation in psychosocial services. The recent Audit Commission report (2002) found that less than 50 per cent of clients have care plans.

Thus it may be that many clients who are currently not responding to their current methadone treatment episode may achieve better outcomes by optimising their existing oral methadone maintenance treatment. Some prescribing may also be occurring in a context which does not provide opportunities for the development of fully integrated care planning to meet a range of health, social care and other needs to enable patients to move to healthier lifestyles.

The recent introduction of buprenorphine as a safe and effective treatment approach in the management of heroin dependence suggests that some patients who have not stabilised on oral methadone may find buprenorphine to be a suitable alternative.

6 Provision of injectable maintenance prescribing

This document sets out eight principles that should underpin the provision of injectable services. These are listed in full on page 10. This section deals with issues around licences and models of care delivery.

6.1 Licences

The expert group recommended that there should be a review of the current licensing system with a view to widening the requirement to include all injectable opioids prescribed for the purpose of drug treatment.

The expert group also made recommendations that any new system for approval of a licence should be more transparent and include criteria that demonstrate the competence of practitioners. Provisions for regular review of licences were recommended.

The expert group also recognised that changes to licensing should not prevent the development of new models of injectable maintenance treatment. An exploration of new models of delivery was advocated including shared care models involving partnerships between specialist drug treatment services and GPs.

It is important to acknowledge the current shortage of specialist doctors. This must be addressed if the UK is to increase injectable prescribing and provide adequate national coverage in terms of clinical advice, supervision, mentoring and clinical governance.

6.2 Models of delivery

Whilst the principles underlying the delivery of injectable opioid treatment are clear, there was no clear consensus in the expert group concerning the best models of service delivery of this new drug treatment modality. This was thought to require further work.

Discussion and debate within the expert group centred around a number of models. The group felt that there was great potential in providing injectable drug treatment from highly centralised injectable clinics (adapted from Swiss and Dutch international models and recent British “injectable clinics” (Strang et al 2000, Metrebian et al 1998).

There was also discussion of other models that could be developed including community-based services which may involve partnership between specialist drug services and GPs. It was generally felt that it would be possible to develop such models in line with the eight key principles, but this would require further development.

The requirement for daily or multiple daily attendance was also discussed as requiring a significant change in current British provision (particularly out-of-office hours). Whilst such requirements may encourage the patient to progress towards improved outcomes, they are also very restrictive of liberty and represent a significant, but positive, change from previous practice in England.

6.2.1 Considerations around a European style injectable clinic model

Some advantages of a European style injectable clinic model were thought to be:

- the tighter control allowed for greater clinical risks to be taken (e.g. higher doses to be administered in safety)
- greater opportunity for other interventions to improve health and social functioning
- clinical trials could take place easily (e.g. if eligibility criteria were to be expanded to other potential patient groups, this could be tightly controlled).

However, implementing this model is likely to require significant new resources. It may be impossible to provide more than a handful of such clinics in the first instance.

6.2.2 Considerations around the community-based model

The expert group expressed concerns that community-based models may run the gauntlet of repeating what was seen as some of the mistakes of the previous "British system" unless they were tightly based on the eight key principles. Previous mistakes to be avoided were cited as: maintaining some patients in inherently risky injecting lifestyles without providing sufficient services or motivation to improve health or social functioning; and inadequate supervision of consumption, care planning and monitoring of patients. Clinicians in the expert groups also give examples of safety measures which could be employed such as occasional supervision of consumption and insisting on the return of used ampoules.

6.2.3 Considerations about existing patients receiving injectable prescriptions

There was general agreement that some current practice concerning the provision of injectable maintenance treatment was less than ideal. Improvements are needed to meet the eight key principles. This is likely to require carefully agreed local planning including commissioners and providers.

Protecting the interests and maintaining stability of those patients who already receive injectable maintenance drug treatment were thought to be very important. The expert group has begun some work in this area.

Conclusion

In conclusion, it is clear that further work needs to be undertaken to develop new models of provision of injectable maintenance drug treatment. *Models of care* (NTA 2002) should provide better drug treatment systems in each area including care co-ordination and may go some way to resolving some of the issues. **The expert heroin group was unequivocal that this form of treatment should be provided in line with the eight key principles or should not be provided at all**. It was speculated that models could be developed which were in line with the eight key principles and be applicable to a wider variety of settings, including urban, semi-rural and rural areas.

7 Clinical eligibility and management

The expert group came to consensus on some issues concerning eligibility criteria, precautions and outcome measures in injectable maintenance opioid drug treatment. Detailed guidance on issues such as dose, prescribing combinations of oral and injectable preparations, etc, will be the subject of further work and NTA and Department of Health guidance[1].

7.1 Eligibility criteria

7.1.1 Inclusion criteria for injectable opioid maintenance

Clients should meet all of the following inclusion criteria in order to be eligible for injectable opioid maintenance:

- The client should have a protracted history (> 3 years) of heroin dependence and regular daily injecting.
- The client should be aged 18 or over.
- The client should be able to provide informed consent. This includes no active medical or psychiatric condition impairing the patient's capacity to provide informed consent
- The client should be willing to comply with the conditions of injectable opiate treatment[2], including:
  - a treatment plan
  - regular supervision and monitoring
  - avoidance of persistent injecting in high risk areas (e.g. neck or groin veins)
  - continuation of injectable treatment being conditional upon positive healthy response to treatment (which includes other treatment elements in a package of planned, co-ordinated care)
  - diversion of the prescribed injectable drugs and "double scripting" being grounds for discontinuation of injectable treatment.
- The client should first have received optimised oral maintenance treatment - an adequate period (normally at least six months and for some this could be significantly longer) of optimised conventional substitution maintenance treatment and associated package of care.
- There should be a persistence of poor treatment outcomes despite a current optimised oral maintenance treatment episode. Indicators of poor outcomes may include:
  - continued frequent (daily or almost daily) injecting of illicit heroin or other opioids
  - patients at continuing high risk of the transmission of HIV, HBV or HCV to themselves or others
  - continuing injecting-related health problems (e.g. abscesses, cellulitis, systemic infections), poor general health, poor psychosocial functioning and drug-related criminality.

If the inclusion criteria are met injectable opioid maintenance treatment may then legitimately be considered by the clinician, in consultation with the patient, key carers and the relevant multidisciplinary team.

2 This includes compliance with DVLA regulations concerning restrictions on driving. To this end, the NTA is collecting clinical protocols from practitioners in England and other countries for reference and welcomes contributions.

7.1.2 Precautions

The following precautions should be considered when prescribing injectable heroin or methodone.

- Caution should be exercised in prescribing any opioids to patients with acute medical conditions such as severe respiratory, hepatic or renal disease, acute abdominal conditions, following recent head injury, and in the elderly. The greater inherent risks of overdose with injectable treatments should be considered in each case.
- Extreme caution should be exercised in prescribing injectable opiates to patients with injecting-related systemic infections (e.g. septicaemia, endocarditis, pneumonia, infective osteomyelitis), and in individuals with coagulation disorders (e.g. patients prescribed anticoagulants, severe hepatic disease, deep vein thrombosis). Oral treatment options should be preferred for such patients.
- Treatment with injectable opiates is more difficult for those patients routinely using multiple drugs (e.g. crack or benzodiazepines) where illicit heroin use is but one of the many drugs being misused. Such patients may benefit from a range of additional interventions (e.g. structured psychosocial interventions for crack misusers or inpatient stabilisation as part of an integrated care package).
- Caution should be exercised in patients who are alcohol dependent or who are misusing benzodiazepine and sedative drugs due to risk of overdose etc. Similarly clinicians should carefully consider the drug interactions of those receiving medication for the treatment of mental health problems such as anti-psychotics.
- Caution should be exercised with pregnant women or women who become pregnant whilst in receipt of an injectable prescription.
- Caution should be exercised in prescribing injectable opiates to patients who cannot safely self-administer their medications, either due to inadequate venous access in 'low-risk' sites (with injecting in neck or groin veins), or persistently poor injecting technique.

7.2 Outcome measurements

The following table presents some suggested outcomes which should be sought by patients receiving injectable opioid maintenance drug treatment. It also suggests some possible tools for monitoring outcomes. All patient outcomes should be monitored in line with the recommendations within *Models of care* (NTA 2002).

Desired outcome	Monitoring tools
Retention in treatment	Care plan and National Drug Treatment Monitoring System (NDTMS)
Reduction in illicit drug use	Regular self reporting Urine, oral fluid or hair tests to monitor other opiate and other illicit drug use, opiate contaminants in street heroin (noscopine, codeine, thebaine on chromatography) Alcohol breath testing
Reduction in hazardous injecting	Regular examination of arms, legs and groins for injecting marks and damage
Improvements in physical and mental health	Knowledge of HBV and HCV status Reduction in adverse injecting related health events Compliance with HBV vaccination Compliance with appropriate medical and psychiatric treatment

Improved social stability	Improvement in housing status (e.g. sustaining a hostel tenancy, management of debt) Positive engagement with other agencies where necessary (e.g. social services) Improved employment or education status Improvement in relationships and social functioning
Reduced criminal activity	Regular self reporting Reduction in arrests Liaison with criminal justice agencies (e.g. probation)

7.3 Optimised oral maintenance drug treatment

The expert group deemed it important to describe good quality or optimised oral maintenance drug treatment in order to be explicit about what would constitute failure from oral drug treatment and warrant a trial with injectable drug treatment. Appendix 2 provides a more comprehensive outline of this.

In summary, the expert group identified, from the evidence base, four key factors in optimised oral methadone treatment. These are services which:

- offer adequate doses of methadone, following assessment and following clear protocols for increasing doses. For example doses of 60 to 120mg of oral methadone daily (in particular over 80mg) have consistently been shown to be more effective than lower doses
- provide adequate levels of supervision and monitoring of clients
- strongly encourage involvement in psycho-social services
- have competent staff that can develop positive therapeutic relationships with patients.

The expert group was keen to note that evidence indicated a tendency among current English practice to under dose patients in oral methadone maintenance or place clients on enforced reduction regimes. Some evidence indicated that this may also occur in patients with injectable heroin and methadone treatment.

The group wished to stress that regimes which enforced detoxification or slow reduction regimes on patients were associated with poor outcomes and relapse, which could place the patient at increased risk of drug-related death due to overdose.

Appendix 2 provides details of optimised oral maintenance drug treatment.

Appendix 1

Excerpts from the Department of Health's *Drug misuse and dependence – Guidelines for clinical management* (1999) pp 55-57

Injectable prescribing for maintenance purposes

a. General issues

No injectable preparations are licensed for use in the management of drug dependence.

This is a controversial area where further research is required to guide rational clinical practice. However, despite such lack of evidence there is a view that a small number of long-term injectors can benefit from such prescribing.[12,13] The idea that prescribing injectables is one point on a continuum, which has being drug free at its opposite end, is attractive, but it is clear that many doctors experience great difficulty in moving patients along the desired treatment path.

There are currently no clear criteria to guide such decision making but repeated failure within existing treatment regimens is the most commonly quoted instance. Failure to engage previously in any form of treatment in the context of severe and long-standing problems can also give rise to consideration of use of injectable medication. When a clinician embarks on such prescribing it should be against a background of a long and persistent history of injecting drug use, and in all cases there should be clear goals that can be assessed at defined intervals.

Means should exist to supervise and monitor, in a clinical setting, the administration of the drug in the early stage of treatment, and at later stages where concern over clinical progress arises. Where pharmacy dispensing occurs, it should be daily to reduce the risk of diversion. Where evidence of diversion exists, daily supervised forms of medication should be re-established.

In the absence of demonstrated significant superior outcomes from this form of clinical practice, and in recognition of the greater inherent dangers and the cost burden of such prescribing, services should regularly audit and review outcomes against set performance standards.

Specialist prescribing injectable formulations should bear in mind that, once initiated, they are likely to become a long-term clinical commitment. Such long-term high resource commitment needs to be taken into consideration when initiating prescribing.

There is no recognised indication for prescribing amphetamines, cocaine or benzodiazepines.

b. Injectable methadone

Injectable methadone has a very high currency in the illicit market, therefore all the clinical issues contributing to compliance and security apply particularly to this form of the drug.

These could include:

- daily dispensing in most situations
- regular monitoring of the patients condition
- the use of plasma methadone levels.

Prescribing injectable methadone is a clinical decision to be made on the basis of the suitability of the individual patient.

12 Martine E., 'Prescribing injectable opiates. Substance Misuse Management in General Practice' *Newsletter issue No 4*, 1997

13 Department of Health. *Task Force to review services for drug misusers: report of an Independent Review of Drug Treatment Services in England*. London: Department of Health 1996 (Chairman: The Reverend Dr John Polkinghorne)

The following issues relating to the patient should be taken into account:

- Is this an appropriate manner of patient engagement?
- If there is evidence of poly-substance misuse, including alcohol dependency, the risks of overdose need serious consideration
- Determination and persistence of patient to continue injecting
- Severe opiate dependence
- Reasonable venous access
- Absence of deep vein thrombosis and related pathologies
- Evidence of reasonable knowledge of the principles of safe injecting.

Additionally, the following issues, relating to the prescriber, should be considered:

- The level of training defining competence to prescribed injectable methadone.
- Are there reasonable, clearly defined and measurable patient goals within a broader psychosocial framework?
- The appropriate Home Office licence may be required to prescribe injectable methadone.

Conclusions

- There is a very limited clinical place for prescribing injectable methadone.
- There are no simple criteria for prescribing injectable but rather a complex clinical decision based on the suitability of each individual patient.
- Prescribing injectables has costs (prolonging dependence, collusion with the drug culture, problems of misuse and diversion) and so the benefits (health gain, reduced criminality, engaging more entrenched users) must be clear.

c. Diamorphine (heroin)

A short-acting opiate agonist, mainly used intravenously, but can also be taken in oral form and inhaled. It is used as part of a maintenance regime in a minority of patients. A Home Office licence is required for such prescribing, which is the preserve of specialists. Diamorphine should only be prescribed in situations of rigorous monitoring and where use in the initial stages can be supervised. With the availability of injectable methadone, there is very little clinical indication for prescribed diamorphine. All the caveats and criteria discussed with regard to injectable methadone apply to diamorphine.

Appendix 2

1 Optimised oral maintenance drug treatment

From the evidence base, the NTA/Department of Heath expert group identified four key factors in the provision of good quality or optimised oral methadone treatment. In summary these are:

- Services that offer adequate doses following assessment and follow clear protocols for increasing doses. For example doses of 60mg to 120mg of oral methadone (in particular above 80 mg) have consistently been shown to be more effective than lower doses. It is important to assess the dosage requirements on the basis of an adequate assessment for each individual. This should include consideration of both safety issues and the likely effectiveness of prescribing. Under-prescribing may be as dangerous as over-prescribing.
- Services that provide adequate levels of supervision and monitoring of clients. Following assessment and stabilisation, regular treatment review and monitoring is essential to adequate care planning and co-ordination. Supervised consumption and dosing is an important safety measure, particularly during induction and stabilisation periods or for 'unstable' clients.
- Services that strongly encourage involvement in psycho-social services (e.g. counselling and social support) tend to have patients with better outcomes.
- Services with competent staff that can develop positive therapeutic relationships with patients.

2 Components of optimised oral maintenance drug treatment

2.1 Assessment, care planning and co-ordination

Treatment for drug misuse is expected to conform to the guidance provided by *Models of care* (NTA 2002), framework for commissioning adult drug treatment systems in each drug action team area in England. Comprehensive assessment, review and multidisciplinary discussion is required in all patients considered for injectable maintenance prescribing in order to establish a treatment plan, set treatment goals and monitor treatment outcomes.

All such patients should receive Tier 3 care planned structured care with some requiring further care co-ordination if a range of needs is identified. Access to other treatment modalities may be required in the context of an integrated care plan. In particular clients who cannot stabilise in the community may require access to in-patient resources to provide comprehensive assessment, titration and stabilisation on substitute drugs.

2.2 Substitute drugs and doses

Building on the clinical guidelines, the expert group described optimised oral maintenance in the following terms:

- Oral maintenance substitution medication involving oral methadone and/or buprenorphine
- Adequate doses of substitution medication: Following assessment, this may require increasing doses to 60 – 120mg of oral methadone (or 16mg of buprenorphine or more) for a significant period of time (normally six months)
- Conventional substitution maintenance with a full agonist (e.g. methadone) should be attempted prior to considering injectable opiate maintenance with a full agonist (e.g. heroin or methadone). Hence, a client not responding to buprenorphine treatment may benefit from transfer to conventional methadone treatment. A client on relatively low doses of methadone (e.g. < 40mg) who refuses to increase their methadone dose (e.g. due to side effects) can generally safely transfer to buprenorphine, whereupon high doses can be used. Clients on higher methadone doses of over 40mg cannot easily attempt an episode of buprenorphine treatment, and may be suitable for injectable treatment without a trial of buprenorphine.

2.3 Supervised consumption

In line with the *Clinical guidelines*, frequent supervision of dosing (e.g. most days of the week) may be required in optimised methadone treatment for the first three months or until the client is stable. This should include supervised consumption on site in the drug service and/or pharmacy-based supervised consumption.

If consumption is at a local retail pharmacy, this should be formally agreed. Adequate premises are required and support for the pharmacy staff should be provided if necessary. There should be clear, agreed and transparent criteria for staff and patients for transfer to unsupervised consumption and also for transfer to shared care arrangements. In the absence of suitable arrangements for supervised consumption of oral opiate treatment it may be difficult to provide optimised oral treatment in the community in some cases.

2.4 A range of other health, psycho-social and other services for optimised treatment

A range of other drug (and alcohol) and other generic services should be available in a local system, in line with *Models of care* (NTA 2002).

The patient is expected to attend regularly for medical reviews and other reviews with workers identified in the care plan. The patient would be encouraged to receive a range of other appropriate interventions within a care-planned package. This may include:

- structured counselling or other psycho-social interventions
- adequate primary health care and antenatal services
- harm reduction services including hepatitis screening and vaccination
- other support around social functioning (that may include family support, housing, education and employment support).

Optimised oral maintenance treatment may involve a range of levels of interventions to provide for changing needs of the individual during the course of treatment. Commissioners and providers should ensure availability of services and ease of access so that all patients can attend and establish more appropriate daily activities. This may require evening opening for those stable patients engaged in work, and access to childcare facilities and flexible regimes for parents. Service users and unpaid carers should be involved in any consultation regarding service developments.

2.5 Competent staff

All staff should be appropriately competent in drug and alcohol treatment provision. The new Drug and Alcohol National Occupational Standards (DANOS) standards (Skills for Health 2003) outline key competencies for practitioners. Doctors should be competent in drugs and alcohol in line with the *Clinical guidelines*. Each local drug action team area is advised to have doctors at all three levels of competency (i.e. generalists, specialised generalists and specialists)[1].

Particular attention is draw to the competency of staff and services as follows:

- Competent staff should be able to develop beneficial, stable therapeutic relationships with patients
- Staff teams should have appropriate skills mix and have competent medical staff to take responsibility for prescribing intervention
- Staffing considerations should include adequate supervision and support, multi-disciplinary training and development, and clinical governance to ensure safe practice.

2.6 Adequately resourced services

The expert group recommended commissioners and providers ensure the following are considered to ensure adequate provision of optimised oral maintenance drug treatment:

1 See Department of Health: *Drug misuse and dependence: guidelines on clinical management*, and NTA's *Resource pack for commissioners*, briefing 3.6 on community prescribing.

- Safe and appropriate premises
- Good access to other treatment modalities without lengthy waiting
- Supervised consumption facilities
- Appropriate length of treatment determined by the treatment needs of the individual patient and not restricted by funding.

2.7 Good clinical protocols and procedures

Appropriate clinical protocols and procedures should be in place to fit within local and national guidance and standards and to meet medico-legal requirements. This will also include the implementation of clinical governance requirements.

2.8 Criteria for failure of oral maintenance and eligibility for injectable maintenance

If the optimised treatment package with oral medication fails to achieve stability in the individual patient there should be a defined period of enhanced assessment and further treatment consideration including further multi-disciplinary assessment, and additional consideration of dose and psycho-social interventions.

It is only following failure of optimised oral drug treatment and care (in patients meeting the eligibility criteria described in section 7.1) that injectable prescribing may be commenced. However, in some patients alternative modalities would be offered (e.g. residential rehabilitation).

Whilst the decision to continue treatment lies with the prescribing doctor and multidisciplinary team, it is important to recognise that enforced detoxification or reduction regimes are associated with relapse and poor outcomes.

The decision to offer injectable opiates must take all factors into account for each patient.

References

Advisory Council on the Misuse of Drugs (2000), *Reducing drug-related deaths*, London, Stationery Office.

Audit Commission (2002), *Changing habits: the commissioning and management of community drug treatment for adults*, London, the Audit Commission.

Battersby, M., Farrell, M., Gossop, M. et al (1992), 'Horse trading: prescribing injectable opiates to opiate addicts – a descriptive study', *Drug and Alcohol Review*, 11: 35-42.

Beaumont, B. (2001), 'Survey of injectable methadone prescribing in general practice in England and Wales', *International Journal of Drug Policy*, 12: 91-101.

Carnworth, T. and Merrill, J. (2002), 'Dose equivalents in opioid substitution treatment', *International Journal of Drug Policy*, 13: 445-447.

Department of Health (1999), *Drug misuse and dependence: guidelines on clinical management*, London, Stationery Office.

Ford, C., and Ryrie, I. (1998), 'Prescribing injectable methadone in general practice', *International Journal of Drug Policy*, 10: 39-45.

Martin, E., Canavan, A. and Butler, R. (1998), 'A decade of caring for drug users entirely within general practice', *Journal of Substance Abuse Treatment*, 13: 521-31.

Metrebian, N., Carnwath, T., Stimson, G. and Storz, T. (2002), 'Survey of doctors prescribing diamorphine (heroin) to opiate-dependent drug users in the United Kingdom', *Addiction*, Vol 97, Nr 9, Sept.

Metrebian, N., Shanahan, W., Wells, B. and Stimson, G. (1998), 'Feasibility of prescribing injectable heroin and methadone to opiate-dependent drug users: associated health gains and harm reductions'. *Medical Journal of Australia* 168: 596-600.

Myton, T. and Fletcher, K. (2003), 'Descriptive study of the effects of altering formulation of prescribed methadone from injectable to oral', *Psychiatric Bulletin*, 27: 3-6.

National Treatment Agency (2002), *Models of care for treatment of adult drug misusers*. Framework for developing local systems of effective drug misuse treatment in England, London, NTA.

Perneger, T.V. et al. (1998), 'Randomised trail of heroin maintenance programme for addicts who fail in conventional drug treatments', *British Medical Journal*, 317: 13-18.

Sell, L., Segar, G. and Merrill, J. (2001), 'One hundred and twenty five prescriptions for injectable opiates in the North West of England', *Drug and Alcohol Review*, 20: 57-66.

Strang, J. and Sheridan, J. 'Effect of government recommendations on methadone prescribing in south east England: comparison of 1995 and 1997 surveys', *British Medical Journal*, 317: 1489-90.

Strang, J., Sheridan , J. and Barber, N. (1996), 'Prescribing injectable and oral methadone to opiate addicts: results from the 1995 national postal survey for community pharmacies in England and Wales', *British Medical Journal*, 313: 270-2 (3 August).

Strang, J., Marsden, J., Cummins, M. et al. (2000), 'Randomised trail of supervised injectable versus oral methadone maintenance: report of feasibility and 6 month outcome', *Addiction*, 95: 1631-45.

Strang, J. and Tober, G. (Eds), (2003), *Methadone Matters: evolving practice of community methadone treatment of opiate addiction*, Martin Dunitz.

Uchtenhagen, A. (1999), *Prescription of narcotics for heroin addicts*. Main results of the Swiss National Cohort Study, Basel, Kartger.

Uchtenhagen, A. (1999), *Prescription of narcotics for heroin addicts*. Main results of the Swiss National Cohort Study, Basel, Kartger.

Van den Brink, W. et al. (2002), *Medical co-prescription of heroin: two randomised controlled trials*, Utrecht, Central Committee.

Ward, J., Mattick, P. and Hall, W. (Eds), (1998), *Methadone maintenance treatment and other opioid replacement therapies*, Martin Dunitz.

National Treatment Agency
5th Floor, Hannibal House
Elephant and Castle
London SE1 6TE
Tel: 020 7972 2214
Fax: 020 7972 2248
nta.enquiries@nta.gsi.gov.uk
www.nta.nhs.uk

All NTA publications and updates on our activities are available on www.nta.nhs.uk.

May 2003

Design: Moore-Wilson www.m-w.co.uk